



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice to Announce Tribal Consultation for an *All of Us* Research Program Update and to Discuss the Program's Policies and Protections Around Data Access and Use Statement for Fiscal Year 2023

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS), National Institutes of Health (NIH) hereby gives notice that the *All of Us* Research Program will be hosting a virtual Tribal Consultation with American Indian and Alaska Native (AI/AN) Federally Recognized Tribes. The consultation will include an update on our approach to Tribal engagement, discussion about integrating data from self-identified AI/AN participants in the program's data platform, the *All of Us* Research Hub at <https://www.researchallofus.org>, and program planning.

DATES: Thursday, September 28, 2023, from 1 to 3:00 p.m. ET. Written Tribal testimony is due by October 28, 2023.

ADDRESSES: Registration links are available on our Tribal Engagement website at <https://allofus.nih.gov/tribalengagement>.

Elected Tribal Officials are encouraged to submit written testimony to AOUTribal@nih.gov.

Please submit on Tribal letterhead by October 28, 2023, with the subject line "*All of Us* Tribal consultation written response."

FOR FURTHER INFORMATION CONTACT: Dr. Joshua Denny AOUTribal@nih.gov, 301-827-9737. More information is available at <https://allofus.nih.gov/tribalengagement>. The *All of Us* Tribal Engagement team may also be reached by email at AOUTribal@nih.gov, or by mail at *All of Us* Research Program, Division of Engagement and Outreach, Tribal Engagement, NIH, 6710-B Rockledge Drive, 4th Floor, Bethesda, MD 20817.

SUPPLEMENTARY INFORMATION:

I. Background Information

The *All of Us* Research Program aims to accelerate health research and medical breakthroughs to enable an era of precision medicine for all. *All of Us* is committed to ensuring the program reflects the diversity of the United States.

In the 21st Century Cures Act (Pub. L. 114-255), Congress authorized NIH to carry out the Precision Medicine Initiative, which includes the *All of Us* Research Program. The law provides NIH with critical tools and resources to advance biomedical research across the spectrum, from foundational basic research studies to advanced clinical trials of promising new therapies, in part through the establishment of a diverse cohort of individuals to support the goals of *All of Us*.

II. Tribal Virtual Informational Presentations and Discussions with Tribal Communities

In June 2023, *All of Us* held four information and discussion sessions virtually to continue to engage with Tribal Nations and rural and urban AI/AN communities. Recorded sessions will be made available at <https://allofus.nih.gov/about/diversity-and-inclusion/tribal-engagement>.

III. Questions:

A. Management and sharing of self-identified AI/AN data (without Tribal affiliation)

1. Integrating information from self-identified AI/AN participants in our data platform, the *All of Us* Research Hub at <https://www.researchallofus.org>.
 - a) How can the program augment the current policies and protections for self-identified AI/AN participant data so that it can be shared with researchers?
 - b) What additional policies or guidance would you like *All of Us* to consider around the use of data from self-identified AI/AN participants?

2. Honoring Tribal sovereignty when working with self-identified AI/AN individuals who consent to participate
 - a) What kinds of protective practices and measures can be implemented to avoid infringing upon Tribal sovereignty when collecting or working with individual participant data?
 - b) How should the program manage and share data from self-identified AI/AN individuals who choose to participate in the program, including those who are living off Tribal lands and/or who are not affiliated with a federally recognized Tribe?

B. Tribal engagement and outreach

1. Possible future marketing efforts in zip codes that overlap on Tribal land and areas bordering Tribal land
 - a) How should the program guide engagement and outreach efforts where zip codes overlap with Tribal land?
2. Program activities for individual participants on Tribal land
 - a) What protocol should be followed when individual participants request program materials to be mailed to them or request home visits on Tribal lands?

C. Program planning activities

1. Future inclusion of children in the *All of Us* Research Program
 - a) What unique considerations are there for the future inclusion of AI/AN infants, children, and adolescents as participants in the program, given that a child's parent or legal guardian must be a current participant?
 - b) What unique considerations are there for family-based enrollment in the research program (e.g., parent or legal guardian participating with their child)?
 - c) What specific factors should be taken into account when enrolling families in the research program, considering the possibility of kinship caregivers or non-traditional child care arrangements for the child?

2. AI/AN traditional blessing ceremony for biosamples of participants who withdraw from the program
 - a) How should the program proceed in conducting a traditional blessing ceremony for the participants who self-identify as AI/AN and request a blessing ceremony prior to the biosample disposition?

Dated: June 22, 2023.

Tara A. Schwetz,

Acting Principal Deputy Director,

National Institutes of Health.

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